COMMISSIONER FOR PATENTS
UNITED STATES PATENT AND TRADEMARK OFFICE
P.O. BOX 1450
ALEXANDRIA, VA 22313-1450

#27

Charles Van Horn Finnegan Henderson Farabow Garrett & Dunner, LLP 1300 I Street NW Washington DC 20005-3315 Re: Patent Term Extension
Application for
U.S. Patent No. 4,668,669

MAILED

JAN 1 6 2004

Dear Mr. Van Horn:

REEXAM UNIT

A certificate under 35 U.S.C. § 156 is enclosed extending the term of U.S. Patent No. 4,668,669 for a period of 1,333 days. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the Patent Information set forth in the Green Book (FDA Approved Animal Drug Products). Effective August 18, 2003, patent submissions for publication in the Orange Book and Docket *95S-0117 need to be submitted on form FDA-3542 which may be downloaded from the PSC Forms Download Website: http://forms.psc.gov/forms/FDA/fda.html.

Telephone inquiries regarding this communication should be directed to the undersigned at (703)306-3159.

Karin Ferriter
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

Rockville, MD 20852

CC:

David T. Read Health Assessment Policy Staff Acting Director Health Assessment Policy Staff, CDER Food and Drug Administration 1451 Rockville Pike, HFD-7

RE: SYNERCID®

FDA Docket No.: 00N-1251

UNITED STATES PATENT AND TRADEMARK OFFICE

(12) CERTIFICATE EXTENDING PATENT TERM
UNDER 35 U.S.C. § 156

(68) PATENT NO.

4,668,669

(45) ISSUED

May 26, 1987

(75) INVENTOR

Jean-Claude Barriere, et al.

(73) PATENT OWNER

Aventis Pharma S.A.

(95) PRODUCT

SYNERCID® (quinupristin and dalfopristin)

This is to certify that an application under 35 U.S.C. § 156 has been filed in the United States Patent and Trademark Office, requesting extension of the term of U.S. Patent No. 4,668,669 based upon the regulatory review of the product SYNERCID® (quinupristin and dalfopristin)(NDA 50-747) by the Food and Drug Administration. Since it appears that the requirements of the law have been met, this certificate extends the term of the patent for the period of

(94)

1,333 days

from January 10, 2006, the original expiration date of the patent, subject to the payment of maintenance fees as provided by law, with all rights pertaining thereto as provided by 35 U.S.C. § 156(b).



I have caused the seal of the United States Patent and Trademark Office to be affixed this 7th day of January 2004.

JAMES E. ROG

Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office